



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/415,890 | 10/08/1999 | BORJE S. ANDERSSON | UTXC:528--1 | 5425 |

32425 7590 05/15/2006
FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER

LEVY, NEIL S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/415,890

Applicant(s)

ANDERSSON, BORJE S.

Examiner

NEIL LEVY

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/31/06 by the Board of Appeals.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 94-97,99 and 106-150 is/are pending in the application.
- 4a) Of the above claim(s) 94-96,106-115,123-132,138-140 and 144-149 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 97,99,116,117,119,121,122 and 133 is/are rejected.
- 7) ☒ Claim(s) 118,120,134-137,142,143,150 is/are objected to.
- 8) ☒ Claim(s) 94-97 and 106-150 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This case has been returned to the examiner by The Board of Appeals.

Election/Restrictions

Claims 94-96, 106-115, 123-132, 138-140 & 144-149 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention & species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on paper # 19.

Claim 118, 120, 134-137, 141, 142, 143, 150 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims

Claim Rejections - 35 USC § 103

Claim 97, 99, 116, 117, 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janoff et al 6405713

Janoff's other method (column 11, last paragraph; column 12, top) selects a solvent and drug and mixes with a lipid solution and buffered aqueous solution, (PBS) steps – a & b – of claim 97; then evaporates off the solvent (step c); evaporation would remove all solvent, thus less than 50%. This is followed by adding PBS (step d). The difference from claim 97, is a drug is present. Under comprising language, it is permitted, and 99 is pimaricin added-Janoff adds pimaricin as the first specified polyene antibiotic (column 9, lines 37, 38) thus obvious to the artisan to involve the specified agents in column 9, as the exemplified drug in column 11. The instant claim 116 is to a lipid solution; so is Janoff's other method (column 11, line 60.)

Preparation includes -sonification- of the DMPC:DMPG in solution, thus, the result can comprise an aqueous-lipid emulsion, also of claim 117, or water (claim 116) as, again, open language is used. Soy as a lipid emulsion source is disclosed at column 8, lines 66, 67.

Art Unit: 1615

1. Claim 97, 99, 116, 117, 119, 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janoff et al 6405713 in view of SZOKA, Jr. 527914.

Janoff (above) utilizes any number of aprotic solvents in methods of preparing pharmaceutically acceptable solvent vehicles, but does NOT mention applicant's equivalent to DMSO, DMA. However, SZOKA shows this equivalency (column 5, lines 8-13) in preparing stable parenteral suspensions (column 6, lines 13-15) of amphotericin, nystatin, and primaricin (column 6, lines 44, 45).

.Double Patenting

Claims 97, 99, 116, 119, 121, 122, 133 are -----
provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim s 45-63
of copending Application No. 10/439252. Although the conflicting claims are not identical, they are not patentably distinct from each other because The same composition is prepared in the manner of the instant, as the composition instantly obtained by the instant methods.

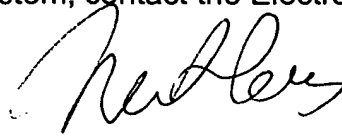
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NEIL LEVY
Primary Examiner
Art Unit 1615
